

1
2 UNITED STATES DISTRICT COURT
3 WESTERN DISTRICT OF WASHINGTON
4 AT SEATTLE

5 KENNETH McGUIRE, On Behalf of Himself
6 and All Others Similarly Situated,

7 Plaintiff(s),

8 v.

9 DENDREON CORPORATION, et al.,

10 Defendant(s).

NO. C07-800MJP

ORDER ON MOTION TO DISMISS
PLAINTIFFS' FIRST AMENDED
CLASS ACTION COMPLAINT

11 The above-entitled Court, having received and reviewed:

- 12 1. Motion to Dismiss Plaintiffs' First Amended Class Action Complaint (Dkt. No. 86)
- 13 2. Defendants' Request for Judicial Notice (Dkt. No. 87)
- 14 3. Lead Plaintiff's Opposition to Defendants' Motion to Dismiss Plaintiffs' First Amended
15 Complaint (Dkt. No. 91)
- 16 4. Lead Plaintiff's Opposition to Defendants' Request for Judicial Notice (Dkt. No. 92)
- 17 5. Defendants' Reply in Support of Their Motion to Dismiss Plaintiffs' First Amended Class
18 Action Complaint (Dkt. No. 94)

19 and all attached exhibits and declarations, makes the following ruling:

20 IT IS ORDERED that the motion is PARTIALLY GRANTED and PARTIALLY DENIED;
21 the insider trading claim and 10(b)/10b-5 claims against Defendant Gold are DISMISSED; the
22 remainder of the motion is DENIED.

23 IT IS FURTHER ORDERED that Plaintiffs will be granted leave to amend to correct the
24 deficiencies noted in this Order. The amended complaint must be filed no later than January 5, 2009.

1 **Background**

2 Defendant Dendreon Corporation (“Dendreon”) is a biotech company focused on development
3 of cancer treatments. FAC ¶¶ 2, 24. Its premier product is “an active cellular immunotherapy for
4 advanced prostate cancer” called Provenge. FAC ¶¶ 41-42. In November 2006, Dendreon submitted
5 a Biologics License Application (“BLA”) concerning Provenge to the Food & Drug Administration
6 (“FDA”), which granted the application “Priority Review status” and a promise of a decision in 6
7 months’ time (by May 15, 2007). FAC ¶ 43.

8 A critical part of the BLA process is a Chemistry, Manufacturing & Controls (“CMC”)
9 inspection, a detailed assessment of the applicant’s manufacturing facility. Def. Ex. A at 12-13. At
10 the conclusion of the CMC inspection of Dendreon’s facility (in mid-February 2007), the inspectors
11 issued a “Form 483,” an “Inspectional Observations Report” which is not issued unless there are
12 “significant objectionable conditions” at a facility. FAC ¶¶ 47, 60. Failure to correct the deficiencies
13 noted in a Form 483 can result in withholding or delaying approval of the BLA. FAC ¶¶ 5, 45, 50.

14 In the wake of the Form 483, Dendreon did a number of things to which Plaintiffs object,
15 among them issuing a Form 10-K for 2006 and a series of press releases, none of which made mention
16 of the February 2007 inspection of their manufacturing site.¹ FAC ¶¶ 60-70.

17 On March 29, 2007, Dendreon held a conference call with investors and securities analysts
18 (following an FDA announcement of preliminary advisory committee recommendations that Provenge
19 was both safe and efficacious). During the course of the call, Defendant Gold (President and CEO of
20 Dendreon) mentioned (for the first time, according the amended complaint) that “the FDA came out
21 and we hosted them for preapproval inspections at our Hanover, New Jersey, facility.” FAC ¶ 75. An
22

23 ¹ The 2006 Form 10-K and the press releases were the subject of a previous motion to dismiss, which was
24 granted. Order Granting Defendants’ Motion to Dismiss the Class Action Complaint, April 18, 2008; Dkt. No. 78.
25 Plaintiffs re-allege those events in their First Amended Complaint; this Order will not re-address those issues, except to
note that they remain insufficient for the reasons stated in the previous Order.

1 analyst then asked: “Okay. Those facilities obviously passed the muster, or can you give us more
2 insight?”

3 Defendant Urdal (Chief Science Officer) responded to the question: “Actually, those are
4 activities that we’ll be discussing with the agency between now and the PDUFA [“Prescription Drug
5 User Fee Act”] date so it’s actually, *we hosted a good inspection*, I think, and we have ongoing
6 discussions between now and between [*sic*] May 15, to finish the review of the CMC section.” FAC ¶
7 77 (emphasis supplied). Again, as with the Form 10-K and the press releases, no mention was made
8 of the Form 483.

9 During the course of that same conference call, Defendant Gold indicated to the participants:
10 “I think the Company has always taken it very much to heart that we want to keep the investment
11 community up to speed and up to date on the information, so as we learn more from the FDA in our
12 discussions with them, we’ll let you know.” FAC ¶ 83. Plaintiffs also point to Gold’s statements
13 during the conference:

- 14 1. “[O]ver the next several weeks we’ll be finalizing our discussion with the FDA and we
anticipate a decision on Provenge by May 15”;
- 15 2. “[R]eally over the next several weeks, we’re working on completing our discussions
with the FDA and anticipate a decision on Provenge by May 15, 2007”; and
- 16 3. “I can give you the classic line that the FDA typically follows the advisory committee’s
17 recommendation. Obviously we look forward to continuing our discussions and
working very closely with the FDA over the next several weeks up to our May 15
18 PDUFA date.” FAC ¶¶ 85-86.

19 Plaintiffs characterize these statements as “materially misleading when made.” FAC ¶ 86. The day
20 after the conference call (March 30, 2007), shares of Dendreon traded heavily and the price of the
21 stock rose as much as 343%. FAC ¶ 12.

22 Four days later (April 2, 2007), Defendant Gold sold 24% of his stock holdings in the company
23 for a total of approximately \$2.7 million. Gold had never sold any of his shares prior to that point.
24 FAC ¶ 13.

1 On May 8, 2007, the FDA issued a “Complete Response Letter” to Dendreon which rejected
2 their request to approve Provenge and cited two reasons for doing so, one of which was the still-
3 unresolved CMC issues. The other (according to Dendreon’s May 9 press release) was the agency’s
4 need for “additional clinical data in support of the efficacy claim.” FAC, ¶ 94; Def. Ex. G, G-7. In
5 support of their characterization regarding the misleading nature of Defendant Gold’s earlier
6 statements, Plaintiffs point to Gold’s May 10, 2007 statement (following the issuance of the Complete
7 Response Letter) that “[t]here was very little interaction between the Company and the Agency
8 between the Panel Meeting and when we received the Complete Response Letter.” FAC ¶ 87.

9 Following the issuance of the Complete Response Letter, the value of Dendreon stock went
10 from \$17.74 a share at opening to \$6.33 by the end of the day. FAC ¶ 95.

11 Defendants held an investor conference call on May 10, 2007. Defendant Urdal revealed the
12 existence of the Form 483 for the first time. He characterized the issues (still unidentified) in that form
13 as “all observations that were made that we think we have well in hand, that none of the issues are
14 ones that will delay the approval process from a manufacturing point of view.” FAC ¶ 96. Plaintiffs
15 characterize this statement as “plainly false: the Provenge BLA could *not* be approved until Dendreon
16 had passed a pre-approval inspection. . . [U]nder Section 351 of the Public Health Safety Act, it is
17 against the law the [*sic*] introduce biologics into commerce from an unapproved facility.” FAC ¶ 98
18 (emphasis in original).

19 Discussion

20 Judicial Notice

21 Defendants have requested that the Court take judicial notice of a long list of documents (see
22 Decl. of Greene, Exs. A-Q), all of which the Court finds are either cited by Plaintiffs in the complaint,
23 matters of public record or were publicly available to investors at the time of the alleged violations.
24 Absent evidence of an improper purpose, such documents are properly subject to judicial notice.

1 Branch v. Tunnell, 14 F.3d 449, 453-454 (9th Cir. 1994); Barron v. Reich, 13 F.3d 1370, 1377 (9th
2 Cir. 1994); Dreiling v. Am. Express Co., 458 F.3d 932, 946, n. 2 (9th Cir. 2006); In re Copper
3 Mountain Sec. Litig., 311 F.Supp. 857, 864 (N.D.Cal. 2004).

4 Plaintiffs' objections to the motion are exclusively concerned with what they consider to be
5 Defendants' erroneous reading of and interpretation of the meaning of the documents.² The Court
6 reiterates its position from the order on Defendants' first motion to dismiss: "The Court takes judicial
7 notice of the requested documents. . . However, the Court will not draw inferences in favor of
8 Defendants from the judicially-noticeable facts." Dkt. No. 78, p. 6.

9 Standard of review

10 A court considering a motion to dismiss an action brought under § 10(b) of the Securities
11 Exchange Act of 1934 ("Exchange Act") accepts all facts in the complaint as true. Tellabs, Inc.. v.
12 Makor Issues & Rights, Ltd., 127 S.Ct. 2499, 2509 (2007). A complaint should not be dismissed if
13 the plaintiffs can prove any set of facts to support a claim that would merit relief. Bell Atl. v.
14 Twombly, 127 S.Ct. 1955, 1065-69 (2007).

15 Section 10(b) of the Exchange Act states that it is unlawful for any person to "use or employ,
16 in connection with the purchase or sale of any security. . . any manipulative or deceptive device or
17 contrivance[.]" 15 U.S.C. § 78(j)(b). Securities and Exchange Commission ("SEC") Rule 10b-5
18 imposes liability on any person who "make[s] any untrue statement of a material fact" or "omit[s] to
19 state a material fact necessary in order to make the statements made, in light of the circumstances in
20 which they were, not misleading." 17 C.F.R. § 240.10b-5(b). A claim under Rule 10b-5 must show:

21
22 ² "Lead Plaintiff does not object to defendants' request for judicial notice inasmuch as defendants seek to show
23 that certain statements were made to investors at certain times, or that FDA regulations or written policies and
24 procedures exist. . . [but] again objects to defendants' attempts to have the Court take judicial notice of documents to
25 improperly resolve factual issues at this stage of the litigation. Defendants have invoked the vast majority of the exhibits
26 as *proof* that Lead Plaintiff's allegations are 'wrong' or 'faulty.'" (Opp. to Jud. Notice, p. 2; emphasis in original.)

(1) a material misrepresentation or omission; (2) made with a wrongful state of mind (i.e., “scienter”); (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation (i.e., a causal connection between the material misrepresentation/omission and the loss).³ Dura Pharm, Inc.. v. Broudo, 544 U.S. 336, 341-42 (2005).

The Private Securities Litigation Reform Act of 1995 (“PSLRA”) imposes heightened pleading requirements on private actions brought under the Exchange Act. Tellabs, 127 S.Ct. at 2508. If a plaintiff alleges that the defendant made a false or misleading statement, his complaint must “(1) specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading;” and (2) “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(1)-(2). A plaintiff who argues that a statement is false or misleading because of an omission must “state with particularity all facts on which [his] belief is based.” In re Silicon Graphics, Inc., 183 F.3d 970, 983 (9th Cir. 1999) Finally, a plaintiff must establish “scienter” by stating “with particularity facts giving rise to a strong inference” that defendants acted either with the “intent to deceive or. . . deliberate recklessness.” Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 987 (9th Cir. 2008). In order for the inference of fraudulent intent to be strong, it must be “more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” Tellabs, *supra* at 2509.

Plaintiffs’ claims: 10(b)/10b-5 violations

This section of the order will examine separately the adequacy of Plaintiffs’ pleadings regarding (1) the “non-scienter” elements of the claims (i.e., whether the regulations were violated) and (2) the existence of scienter (whether Plaintiffs have adequately plead that the defendants possessed the requisite state of mind to establish liability).

³ The Court has previously found the element of “loss causation” to be adequately pled (Dkt. No. 78, pp. 16-17) and declines Defendants’ invitation to revisit that issue.

1 Violations

2 Plaintiffs' FAC differs from its predecessor primarily in its allegations regarding the phone
3 conference held on March 29, 2007 between Defendants Gold and Urdal and a group of investors and
4 analysts. The occasion of the phone conference was the announcement by the FDA's Cellular, Tissue
5 and Gene Therapies Advisory Committee that Provenge had been preliminarily determined to be both
6 safe and efficacious. FAC ¶¶ 71-72.

7 Defendants Gold and Urdal made a number of statements during the course of this exchange
8 which Plaintiffs consider actionable: Gold's statements regarding "the classic line" that the FDA
9 usually follows the advisory committee's recommendation, his comments that Dendreon was
10 "finalizing" or "completing" discussions with the FDA and his assurances that "we want to keep the
11 investment community up to speed and up to date on the information" (FAC ¶¶ 8, 9); as well as
12 Urdal's statements that "we hosted a good inspection" and that "we have ongoing discussions with
13 [the FDA] between now and between [sic] May 15, to finish the review of the CMC section." FAC ¶
14 10.

15 Of the statements made during this phone conference and plead in the FAC, the Court finds
16 only one that is actionable: the "good inspection" statement by Defendant Urdal. The remainder of the
17 pronouncements which Plaintiffs label objectionable suffer from the same defects noted in the previous
18 order – nothing in them states or suggests that Provenge is going to be approved (which would tend to
19 influence the value of the stock), only that a decision is going to be rendered by May 15, 2007. For
20 example, the statement by Defendant Gold, "I can give you the classic line that the FDA typically
21 follows the advisory committee's recommendation," was qualified shortly thereafter by his statement
22 that "[the FDA is] not required to follow the advice of the outside Advisory committee, although as
23 you know, they often do." Def. Ex. F, F-8. There is nothing false or misleading about this statement.

1 Gold's comments regarding how "we want to keep the investment community up to speed and
2 up to date on the information, so as we learn more from the FDA in our discussions with them, we'll
3 let you know," when viewed in the context of the conversation that was occurring, are unambiguously
4 an observation concerning Dendreon's willingness to let the investors and analysts know as soon as the
5 FDA had issued a decision on Provenge. Plaintiffs' attempt to stretch the comment to represent some
6 kind of universal, historical promise that the investors would always be told everything about the
7 approval process is simply not supported in the context of the entire phone conference.

8 However, Plaintiffs' allegations regarding the statement "we hosted a good inspection, I think"
9 are sufficiently well-plead as violations of Rules 10(b) and 10b-5 to survive a motion to dismiss.
10 Defendants are correct that this is a statement of opinion, but incorrect in their legal argument that, in
11 order to be actionable, Plaintiffs must demonstrate that the statement is both "objectively and
12 subjectively false" (In re McKesson HBOC, Inc.. Securities Litigation, 126 F.Supp. 2d 1248, 1265
13 (N.D. Cal. 2000)); i.e., that not only must the inspection not have been "good," but that Urdal himself
14 did not believe that it had been "good."

15 The Court does not agree with Defendants' reading of the cases they cite for this proposition;
16 nowhere does McKesson – or the cases it cites as precedent – say that an opinion statement is *only*
17 actionable if subjectively *and* objectively false. Furthermore, Plaintiffs simply have the stronger legal
18 argument with their citation to In re Apple Computer Securities Litigation, 886 F.2d 1109 (9th Cir.
19 1989):

20 [P]rojections and general expressions of optimism may be actionable under federal
21 securities laws. [*citations omitted*] A projection or statement of belief contains at least
22 three implicit factual assertions: (1) that the statement is genuinely believed, (2) that
23 there is a reasonable basis for that belief, and (3) that the speaker is not aware of any
24 undisclosed facts tending to seriously undermine the accuracy of the statement. A
25 projection or statement of belief may be actionable to the extent that one of these
26 implied factual assertions is inaccurate. Id. at 1113.

1 Defendants argue that Apple Computer only applies to future events, but cite no case authority
2 for that argument. Nothing in the language of the opinion supports that narrow interpretation.

3 Analyzing Urdal's statement in accordance with Apple Computer, the Court finds that:

- 4 1. There are no allegations that Urdal did not believe the statement.
- 5 2. There are insufficient allegations that Urdal did not have a reasonable basis for
6 believing the statement (i.e., Defendants have never disclosed what was in the Form
7 483; Plaintiffs' allegations regarding how serious the Form 483 deficiencies were are
8 speculation only).
- 9 3. Plaintiffs have sufficiently alleged that Urdal was aware of undisclosed facts (the Form
10 483) tending to seriously undermine the accuracy of that statement. It is not necessary,
11 for the purposes of this analysis, to know the contents of the document, simply the facts
12 that the Form 483 (which by agreement of the parties is only issued for "significant
13 objectionable conditions") existed and that Urdal knew of its existence. It is a
14 reasonable inference to draw that not every investor or analyst participating in that
15 phone conference (and not every "reasonable investor" who would thereafter be
16 apprised of the contents of the discussion), upon being made aware that "significant
17 objectionable conditions" had been discovered, would describe an inspection as "good,"
18 regardless of whether the conditions were remediable or the company was undertaking
19 remediation. This prong of the Apple Computer test does not require that the omitted
20 information actually undermine the accuracy of the statement, only that it "tend" to.
21 The Court finds that Urdal's omission meets that test, a finding which draws further
22 strength from the fact that neither Urdal nor Gold ever directly answered the question
23 of whether the facility had "passed muster."

1 Where the claim of 10(b)/10b-5 violation is based on an omission, that which was omitted must
2 make something which was said materially misleading, creating “an impression of a state of affairs that
3 differs in a material way from the one that actually exists.” Brody v. Transitional Hosps. Corp., 280
4 F.2d 997, 1006 (9th Cir. 2002). It is not significant for purposes of this analysis that the contents of
5 the Form 483 *might* have confirmed Urdal’s opinion that it was a “good inspection” (or Plaintiffs’
6 speculation that it was a bad one). Defendants have chosen not to disclose the Form 483 contents, and
7 the Court will not speculate about them. One need not know the contents of an unfavorable report (a
8 fair characterization of the Form 483 under the best of circumstances) to state with a high degree of
9 certainty that the mere fact of its existence would have a negative impact on the hopes and
10 expectations of investors, and thus upon the value of the stock. That is the situation “that actually
11 exist(ed)” on the date that Urdal neglected to inform the participants of the phone conference (and the
12 other members of the investing public) about the existence of the Form 483. His omission of that fact,
13 combined with the failure to answer the question concerning whether the Dendreon manufacturing
14 facility had “passed muster,” created “an impression of a state of affairs that differ[ed] in a material
15 way from the one that actually exist[ed].”⁴ The allegations of that omission are sufficient to find that,
16 for purposes of a motion to dismiss, Plaintiffs have adequately plead a violation of the Exchange Act.

23 ⁴ The Form 483 has already been found to be “material:” “Although the observations in the Form 483 are not
24 final agency determinations and although Plaintiffs have failed to plead how serious the observations were, the
25 disclosure of ‘significant objectionable conditions’ would significantly alter the total mix of information available to the
reasonable investor because it bears on potential delays in the approval of Dendreon’s only near-commercial status
product.” Dkt. No. 78 at 6-7.

1 Scienter

2 A plaintiff must establish “scienter” by stating “with particularity facts giving rise to a strong
3 inference” that defendants acted either with the “intent to deceive or. . . deliberate recklessness.”
4 Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 987 (9th Cir. 2008). In order for the inference of
5 fraudulent intent to be strong, it must be “more than merely plausible or reasonable – it must be cogent
6 and at least as compelling as any opposing inference of nonfraudulent intent.” Tellabs, *supra* at 2509.

7 Defendants muster an impressive array of arguments and readings of FDA regulations and
8 guidelines in support of their assertion that Plaintiffs’ allegations do not adequately plead the existence
9 of the critical element of scienter. They cite to the Court’s previous finding that Gold’s sale of stock
10 was not sufficiently suspicious to create the inference (Dkt. No. 78 at 14-15), that he only sold 25%
11 of his stock and that Urdal did not sell any of his.

12 Defendants repeatedly allude to the absence of any evidence regarding the severity of the
13 findings in the Form 483 and again cite the language of the Court’s previous order that no inference is
14 possible regarding the severity or lack of severity of the “significant objectionable conditions.” Id. at
15 14. They assert that the existence of the Form 483 conditions would not necessarily block or delay
16 approval of Provenge, and that FDA regulations allow for the post-approval remediation of issues
17 raised during the application process.⁵

18 Defendants also argue that the consistency with which Urdal and Gold withheld the
19 information concerning (first) the existence of the Form 483 and (later) the nature of the 483
20 objections is just as likely attributable to their belief (and the reality) that the objections were simply
21 not that serious and their sincere and reasonable belief that the 483 problems could easily be remedied

22
23 ⁵ Defendants assert that FDA provisions permitting “application supplements” and “postmarketing
24 commitments” meant that any uncorrected CMC deficiencies would not necessarily prevent approval of their product.
25 Mtn at 12; Reply at 9. These arguments are unconvincing, as the procedures cited appear to apply to products which are
already approved. 21 C.F.R. § 601.12. BLA approval requires pre-existing compliance of an applicant’s commercial
production facilities. 21 C.F.R. § 601.20.

1 in time to gain approval of their drug. They offer a plausible hypothesis that the reason that the 483
2 issues were not remediated more quickly was that the FDA requirement (enunciated in the Complete
3 Response Letter) that they conduct further clinical trials meant a delay which would necessitate a
4 reinspection of their facilities in a year or two anyway.

5 However, in order to carry their burden on scienter, Plaintiffs do not need to invalidate the
6 inferences which Defendants raise. They only need to create an inference of fraudulent intent which is
7 “cogent and at least as compelling as any opposing inference of nonfraudulent intent.” They have
8 succeeded in doing this.

9 The Supreme Court in Tellabs counsels reviewing courts in private PSLRA actions to consider
10 “the totality of the circumstances” when evaluating the adequacy of pleading regarding scienter. The
11 allegations plead by Plaintiffs which, taken in their entirety, create a cogent and compelling inference
12 of the requisite intent are:

- 13 • *Defendants’ knowledge of the existence of the Form 483* – this Court has already ruled
14 that the mere fact that this document was issued is “material.” Dkt. No. 78 at 6-7. The
15 concealment of material information from investors is probative of a “deliberate
16 recklessness.”
- 17 • *The critical nature of the 483 issues and the likelihood/certainty that, left unresolved,*
18 *they would have delayed FDA approval* – As previously indicated, the Court does not
19 find Defendants’ arguments that the 483 issues would not have held up approval of
20 Provenge to be more compelling evidence of “nonfraudulent intent” than Plaintiffs’
21 evidence to the contrary. Defendants’ argument that an “application supplement”
22 process permits post-approval remediation of application issues is contradicted by the
23 language of the FDA regulations indicating that the “application supplement” process
24 permits post-approval modifications only for changes to an already-approved product.

1 21 C.F.R. § 601.12. Defendants then suggest that the FDA’s “post-marketing
2 commitments” (“PMC”) process is commonplace and permits them to essentially
3 promise to fix the 483 problems post-approval, but nothing in the regulations they cite
4 comports with this interpretation – the PMC process appears to be restricted to
5 marketing *studies* concerning “unaddressed safety and efficacy concerns” (not
6 manufacturing facility deficiencies) following approval of a product. Def. Ex. U at 1.
7 And, as Plaintiffs point out in their complaint, Defendants’ own Form 10-K reflected
8 the corporation’s understanding that facilities issues could indeed thwart approval of a
9 prospective product. FAC ¶ 63 (quoting Defendants’ 2006 Form 10-K).

- 10 • *Defendants’ choice to not disclose the existence of the 483 while characterizing the*
11 *facility review process as a “good inspection”* – The analysis *supra* concerning the
12 misleading nature of this omission is equally applicable to an assessment of “deliberate
13 recklessness” and gives rise to an inference of reckless, conscious misconduct that is at
14 least as compelling as any inference of nonfraudulent intent.
- 15 • *The 483/CMC issues remain unresolved* – More than a year after the issuance of the
16 Complete Response Letter, there is no evidence that any of the concerns (whatever
17 they are) raised in the Form 483 have been addressed. Defendants’ argument
18 concerning the “prioritization” of the issues which they must address for approval (first,
19 the additional clinical trials, *then* any facilities’ problems) certainly militates in favor an
20 inference of non-seriousness and nonfraudulent intent, but (given that the 483 issues
21 *can* delay approval) there is an equally cogent and compelling inference to be drawn
22 that the issues were serious, numerous and potentially fatal to ultimate approval of
23 Provenge.

1 Plaintiffs cite the May 10, 2007 conference call (Defendants' refusal to disclose the exact
2 nature of the 483 issues, claiming they were "proprietary" and "not big issues;" and their statement
3 that the 483 items would not delay approval of Provenge) as further evidence of scienter. The Court
4 does not agree. Even assuming that it is permissible to use evidence which arose *later* in time than the
5 class period to draw inferences about Defendants' state of mind *during* the class period, the inferences
6 of recklessly fraudulent conduct which arise from the content of this conference call are simply not as
7 compelling as the inference that Defendants would have us draw of nonfraudulent intent (that the 483
8 issues were simply not that serious and would be easily resolved prior to approval).

9 Taken in their entirety, however, Plaintiffs' allegations adequately raise an inference of
10 deliberate recklessness which "reflects some degree of intentional or conscious misconduct." In re
11 Silicon Graphics Inc.. Securities Litigation, 183 F.3d 970, 979 (9th Cir. 1999).

12 The Court is aware that none of the statements or omissions found sufficient to adequately
13 plead a PSLRA violation were made by Defendant Gold. Defendants have not contested that Gold
14 was aware of the existence of the Form 483 at the time of the March 29, 2007 conference call.
15 Although the Ninth Circuit has not ruled on the issue, there are courts which have held "that a high-
16 ranking company official cannot knowingly fail to correct a false oral statement made by another
17 official at a conference with analysts or similar setting." In re Infosonics Corporation Securities
18 Litigation, 2007 WL 2301757 (S.D. Cal.), citing Barrie v. Intervoice-B Rite, Inc., 409 F.3d 653 (5th
19 Cir. 2005) and In re SmarTalk Teleservices, Inc. Securities Litigation, 124 F.Supp.2d 527, 542
20 (D.Ohio 2000). The Court finds this reasoning just as applicable to a misleading statement as to a
21 false one, but notes (as the Barrie court did) that Plaintiffs have neglected to plead that Gold failed to
22 correct Urdal's statement. See Barrie, 409 F.3d at 656. Plaintiffs will be permitted to amend their
23 complaint to reflect this allegation should they so choose.

1 **Plaintiffs' claims: Insider trading**

2 To establish liability for insider trading under §§ 10(b) and/or 20a, Plaintiffs must demonstrate
3 two elements:

4 **Sale of stock on the basis of material, nonpublic information:** Plaintiffs have adequately
5 plead this portion of their proof. There is no dispute that the existence of the Form 483 was not public
6 at the time Gold sold his stock, and the Court has already ruled on its materiality.

7 **Contemporaneous trading with Defendant Gold:** To have standing to pursue an insider
8 trading claim under §§ 10(b) or 20a, Plaintiffs must have traded “contemporaneously” with Gold.
9 Neubronner v. Milken, 6 F.3d 666, 670 and n. 5 (9th Cir. 1993). There is no statutory definition of
10 “contemporaneous” and no court has defined the term with any precision. Gold’s stock was sold on
11 April 2, 2007; the subclass period is April 2 - 9 and Lead Plaintiff McGuire’s first trade after April 2
12 was a purchase alleged on April 9 (a lapse of five trading days). Plaintiffs and Defendants agree that
13 contemporaneousness depends on market conditions, and the Court is persuaded by Defendants’
14 argument that the lapse in time is too great.

15 While recognizing that it is without precedential weight, the Court finds this discussion of the
16 rationale behind the “contemporaneousness” requirement very useful in analyzing the
17 “contemporaneousness” issue:

18 The requirement of contemporaneousness developed as a proxy for the traditional
19 requirement of contractual privity between plaintiffs and defendants. [footnote omitted]
20 Since identifying the party in actual privity with the insider is virtually impossible in
21 transactions occurring on an anonymous public market, the contemporaneousness
22 standard was developed to give plaintiffs a more feasible avenue by which to sue
23 insiders. William Wang, *The Contemporaneous Traders Who Can Sue an Inside*
24 *Trader*, 38 Hastings L.Rev. 1175 (1987). The requirement was intended to preserve the
25 notion that only plaintiffs who were harmed by the insider could bring suit, while
26 nonetheless making it possible for such persons to bring suit. While an actual trade
between plaintiff and defendant need not be expressly shown, harm to the plaintiff is a
necessary factor. Such harm may be found where it appears the plaintiff might, in fact,
have traded with the defendant. Buban v. O'Brien, 1994 WL 324093, 3 (N.D.Cal.
1994).

1 Viewed from the “privity” perspective, Defendants’ argument that a high volume of trading
2 and a significant difference in price require a shorter period of time for a finding of contemporaneity is
3 compelling. Between the date of Gold’s sale and McGuire’s purchase, 178,331,300 shares of
4 Dendreon stock were traded, and the price rose from \$14.30/share to \$23.58. Def Ex. I. To make a
5 finding of “contemporaneous” transactions under these circumstances would defeat the purpose of the
6 requirement.

7 Plaintiffs asserted at oral argument that there were members of their class who acquired their
8 Dendreon shares closer in time to Defendant Gold’s sale. They will be permitted to amend their
9 complaint to allege class member stock transactions which are contemporaneous with those of Gold.

10 **Conclusion**

11 Defendants’ motion to dismiss the claims against Defendant Urdal and Dendreon for violations
12 of 10(b) and 10b-5 will be DENIED – Plaintiffs have plead with sufficient specificity facts giving rise
13 to Exchange Act violations and the requisite scienter. The motion to dismiss the claims against
14 Defendant Gold (both for 10(b) and insider trading violations) will be GRANTED, but Plaintiffs will
15 be permitted to amend their complaint to correct the deficiencies regarding those claims noted in this
16 Order. The amended complaint shall be filed no later than January 5, 2009.

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18 The clerk is directed to provide copies of this order to all counsel of record.

19 Dated: December __6__, 2008

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22 Marsha J. Pechman
23 U.S. District Judge
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